

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 3 CASES LISTED ON MOTION EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO
EXCLUDE THE OPINIONS AND TESTIMONY OF DEFENDANT ETHICON, INC.
AND JOHNSON & JOHNSON'S EXPERT STEVEN MACLEAN, PH.D., P.E.**

Defendants Ethicon, Inc. and Johnson & Johnson (“Ethicon”) submit this Response to Plaintiffs’ Motion [ECF 2825 (“Mot.”)] and Memorandum in Support of Their Motion to Exclude or to Limit the Opinions and Testimony of Steven MacLean, Ph.D., P.E. [ECF 2826 (“Mem.”)] (collectively, “Motion”). The cases to which this Response applies are identified in Plaintiffs Motion Exhibit A.

This Court denied Plaintiffs’ Wave 1 *Daubert* motion on all grounds except for their challenge to Dr. MacLean’s calculations related to Dr. Jordi’s testimony, on which the Court reserved ruling. Mem. Op. and Order (*Daubert* Motion re Steven MacLean, Ph.D., P.E.) (S.D. W. Va. Sept. 2, 2016) [ECF No. 2724] (“Wave 1 Order”). For Wave 3, Plaintiffs have adopted their Wave 1 *Daubert* motion, and offered the additional argument that Dr. MacLean should be excluded because he has contradicted the testimony of Ethicon’s Rule 30(b)(6) designee—Dr. Thomas Barbolt. Plaintiffs’ arguments have no basis in law or fact.

I. Adoption of Response

In their Motion, Plaintiffs adopted their Wave 1 *Daubert* motion regarding Dr. MacLean. Mot. at 1. In response, Ethicon hereby adopts and incorporates by reference its *Daubert* Response filed in relation to Dr. MacLean for Ethicon Wave 2, Dkt. 2552, which includes the arguments Ethicon advanced in its Wave 1 response. Ethicon respectfully submits that this Court should deny Plaintiffs' Wave 3 Motion for the same reasons articulated in its Wave 1 Order. *See* Wave 1 Order.

II. Plaintiffs' Attempt To Exclude Dr. MacLean's Opinions Based On The Testimony Of Ethicon's Rule 30(b)(6) Representative Misunderstands Both The Law And The Testimony At Issue.

Plaintiffs claim that the Court should preclude Dr. MacLean from opining about the alleged degradation of Prolene based on the testimony of Dr. Thomas Barbolt, Ethicon's Rule 30(b)(6) representative. *See* Mem. at 1-4.¹ Plaintiffs point to certain excerpts from Dr. Barbolt's testimony regarding surface cracking and degradation, and claim that Ethicon is "bound" by what they characterize as Dr. Barbolt's "admissions" such that it cannot present evidence "contradict[ing]" Dr. Barbolt's testimony. *Id.*² Plaintiffs misconstrue Dr. Barbolt's testimony,

¹ Plaintiffs previously asserted the same argument in their motion to exclude the opinions of Dr. Shelby Thames in Ethicon Wave 2, which they adopted by reference in Ethicon Wave 3. *See* Mem. of Law in Supp. of Plfs' Mot. to Exclude the Opinions and Testimony of Shelby Thames, Ph.D., Dkt. 2458; Plfs' Daubert Mot. to Exclude or Limit the Opinions and Testimony of Dr. Shelby Thames, Dkt. 2839. Plaintiffs' arguments against Dr. Thames fail for the same reasons discussed in this response, as well as in Ethicon's response in opposition to Plaintiffs' motion to exclude Dr. Thames testimony in Wave 2, which Ethicon has adopted by reference in Wave 3. *See* Resp. in Opp. to Plfs' Mot. to Exclude the Opinions and Testimony of Shelby Thames, Ph.D. [ECF No. 2553].

² Plaintiffs also point to certain testimony by Dr. Barbolt regarding the alleged leaching of antioxidants from Prolene fibers into the tissues surrounding the fiber. Mem. at 2. Plaintiffs' leaching argument is irrelevant because Dr. MacLean will not offer affirmative opinions about the alleged leaching of antioxidants. Rather, he will testify about how antioxidants work and how Prolene's antioxidant package retards oxidation *in vivo*. Furthermore, other witnesses will establish that there is no evidence showing that Prolene implanted in the human body has any cytotoxic effect. Should Plaintiffs choose to question Dr. MacLean about leaching, he has the relevant knowledge, education, training, and experience to address this issue.

Ethicon's position, Dr. MacLean's opinions, and the law.

A. Dr. Barbolt's testimony is consistent with Dr. MacLean's opinion and Ethicon's position regarding degradation.

Plaintiffs' argument is predicated on an incomplete and misleading representation of Dr. Barbolt's testimony regarding the alleged degradation of Prolene. A full reading of Dr. Barbolt's testimony shows that he referred to subjective observations of surface cracking, not the objective assessments necessary to establish whether Prolene meaningfully degraded *in vivo*. For instance:

Q. Are you telling the ladies and gentlemen of the jury that when the outer surface of the polypropylene fibers crack and peel away from the surface, that that is not degradation?

...

[A.] I am telling listeners that the key endpoint of adverse effects of degradation are molecular weight and tensile strength, both quantitative measures, not subjective assessments of surface changes, but quantitative measures that hold great weight and suggest that there's no degradation to the Prolene fiber in terms that are significant.

Resp. Ex. A, Barbolt 1/8/14 Dep. 373:24–375:6; *see also id.* at 448:19–449:16 (explaining the study reported “no evidence of degradation that's meaningful.”).

In other words, Dr. Barbolt testified that certain Ethicon tests made subjective observations of surface cracking on some Prolene fibers, but there had been no quantitative test results that showed the Prolene had meaningfully degraded. Thus, Dr. Barbolt's testimony is consistent with Ethicon's position in this litigation, as well as Dr. MacLean's opinion that Ethicon's “Prolene material is not suffering from any quantifiable degradation while *in vivo*.”

Resp. Ex. B, MacLean Report at 94; *see also id.* at 52 (“Ethicon's Seven Year Dog Study data

strongly confirms that Prolene is not experiencing any meaningful degradation *in vivo*, in fact, the material exhibits more ductility and rupture resistance after long-term implantation.”).³

To the extent any distinction exists, it lies solely in Dr. MacLean’s opinion that the cracked surfaces about which Dr. Barbolt testified are composed of a brittle material with biological components that formed due the sample preservation process, and not degraded Prolene. *See* Resp. Ex. C, MacLean 9/29/15 Dep. 202:11-203:8; *see also id.* at 234:23-235:6 (“Q. Do you have an opinion as to what is the cracked layer that is observed on the SEMs? . . . A. Let me tell you what we – what we know. We know that the cracked layer is not oxidized Prolene. We know the cracked layer is not Prolene. And we know it has a biological component to it.”); Resp. Ex. D, MacLean 4/18/16 Dep. 88:21-22 (“We know that there’s a biological component to this crust layer, because it takes on H&E staining.”).

It cannot be said that Dr. MacLean’s opinion—based on his reliable and repeatable testing, as well as his analysis of Dr. Vladimir Iakovlev’s use of histological stains, that was conducted subsequent to Dr. Barbolt’s 30(b)(6) deposition—contradicts Dr. Barbolt’s underlying position that Prolene is not subject to meaningful degradation *in vivo*.

B. Ethicon can properly introduce Dr. MacLean’s degradation opinions.

1. Rule 30(b)(6) testimony does not “bind” a corporation in the same sense as a judicial admission.

Setting aside the factual inaccuracy of Plaintiffs’ argument, their assertion that Ethicon should be precluded from offering Dr. MacLean’s opinions at trial because they purportedly contradict Dr. Barbolt’s testimony as Ethicon’s corporate representative is legally incorrect. Courts and commentators around the country have expressly rejected Plaintiffs’ interpretation of

³ Ethicon anticipates that Plaintiffs will point to certain cherry-picked passages from Dr. MacLean’s deposition in an attempt to create the appearance of a conflict with Dr. Barbolt’s testimony. But the record shows that Dr. MacLean disagreed with passages of Dr. Barbolt’s testimony that were presented by plaintiffs’ counsel out-of-context, with no reference to Dr. Barbolt’s clarification that there is no “meaningful” degradation of Prolene. *See, e.g.*, Resp. Ex. C, MacLean 9/29/15 Dep. 184:6-186:1.

Rule 30(b)(6). Indeed, the weight of authority has adopted the position that Rule 30(b)(6) testimony is not “binding” in the same sense as a judicial admission. *See, e.g., A.I. Credit Corp. v. Legion Ins. Co.*, 265 F.3d 630, 637 (7th Cir. 2001) (“Nothing in the advisory committee notes indicates that [Rule 30(b)(6)] goes so far” as to be “absolutely binding” on a corporation); 8A Charles Alan Wright, Arthur R. Miller & Richard L. Marcus, *Federal Practice and Procedure* § 2103 (3d ed.) (explaining that Rule 30(b)(6) deposition testimony is “not ‘binding’ in the sense that the corporate party is forbidden to call the same or another witness to offer different testimony at trial.”).⁴

Rather, Rule 30(b)(6) testimony is “evidence which, like any other deposition testimony, can be contradicted and used for impeachment purposes” at trial. *Indus. Hard Chrome, Ltd. v. Hetran, Inc.*, 92 F. Supp. 2d 786, 791 (N.D. Ill. 2000); *see also R&B Appliance*, 258 F.3d at 786; *Taylor*, 166 F.R.D. at 362 n.6; Wright & Miller, at § 2103. This rule makes sense especially where, as here, there can be no claim of unfair surprise by Plaintiffs. *See Thornton v. Fed. Deposit Ins. Corp.*, Nos. 1:00-0655, 1:03-2129, 1:04-0043, 2007 WL 391571, at *1 (S.D. W. Va. Feb. 1, 2007).⁵

⁴ *See also Keepers, Inc. v. City of Milford*, 807 F.3d 24, 34-35 (2d Cir. 2015), *petition for cert. filed*, No. 15-1487 (June 9, 2016) (“Nothing in the text of the Rule or the Advisory Committee notes indicates that the Rule is meant to bind a corporate party irrevocably to whatever its designee happens to recollect during her testimony.”); *R&B Appliance Parts, Inc. v. Amana Co., L.P.*, 258 F.3d 783, 786 (8th Cir. 2001) (“Although [a company] is certainly bound by [Rule 30(b)(6)] testimony, it is no more bound than any witness is by his or her prior deposition testimony.”); *Erickson v. Microaire Surgical Instruments LLC*, No. C08-5745BHS, 2010 WL 1881942, at *2 (W.D. Wash. May 6, 2010) (“Rule 30(b)(6) depositions produce evidence, not judicial admissions.”); *Sea Trade Co. v. FleetBoston Fin. Corp.*, No. 03 CIV. 10254 (JFK), 2008 WL 4129620, at *21 (S.D.N.Y. Sept. 4, 2008); *United States v. Taylor*, 166 F.R.D. 356, 362 n.6 (M.D.N.C. 1996) (“When the Court indicates that the Rule 30(b)(6) designee gives a statement or opinion binding on the corporation, this does not mean that said statement is tantamount to a judicial admission.”).

⁵ Although some courts in other jurisdictions have followed the interpretation of Rule 30(b)(6) advanced by Plaintiffs, Ethicon submits that “the better rule is that ‘the testimony of a Rule 30(b)(6) representative, although admissible against the party that designates the representative, is not a judicial admission

As discussed above, Dr. Barbolt's testimony does not contradict Ethicon's position or Dr. MacLean's opinions in this case. But, even if it did, Dr. Barbolt's testimony would not "bind" Ethicon in the sense that it would be barred from offering evidence regarding degradation at trial. *See A.I. Credit*, 265 F.3d at 637. Moreover, Plaintiffs certainly cannot claim unfair surprise, as Ethicon has maintained its position regarding degradation throughout this litigation. *See Thornton*, 2007 WL 391571, at *1. While Plaintiffs may be able to use Dr. Barbolt's allegedly contradictory testimony at trial, they cannot use it as a means of excluding Ethicon's experts.

2. The cases on which Plaintiffs rely do not support their position.

Plaintiffs identify three cases in support for their argument that Ethicon should be precluded from offering Dr. MacLean's opinions at trial, but scrutiny of these decisions demonstrates that they simply do not support Plaintiffs' position in this litigation.

Plaintiffs' reliance on *Spicer v. Universal Forest Prod., E. Div., Inc.*, No. 7:07CV462, 2008 WL 4455854, at *1 (W.D. Va. Oct. 1, 2008) is misplaced. *See* Mem. at 1. In *Spicer*, the court found that the defendant's Rule 30(b)(6) designee conducted no investigation of any of the topics listed in the deposition notice except confer with counsel, who instructed the designee not to answer any questions about the details of those conversations. *Id.* at *2. Finding that the designee exhibited such an "appalling lack of any preparation" to testify that it amounted to an "abject failure [by the party] to comply with the requirements of [Rule 30(b)(6)]," (*id.*), the court held that sanctions were appropriate. *Id.* at *8.

There are no such allegations here. Moreover, nothing in the *Spicer* decision stands for the proposition that a corporate entity is irrevocably bound by Rule 30(b)(6) testimony. In fact, the passage in *Spicer* to which Plaintiffs point is actually a quote from *United States v. Taylor*,

absolutely binding on that party.'" *State Farm Mut. Auto. Ins. Co. v. New Horizont, Inc.*, 250 F.R.D. 203, 212 (E.D. Pa. 2008) (quoting Wright, Miller & Marcus, at § 2103).

which notably explained that “[w]hen the Court indicates that the Rule 30(b)(6) designee gives a statement or opinion binding on the corporation, this does not mean that said statement is tantamount to a judicial admission.” 166 F.R.D. 356, 362 n.6 (M.D.N.C. 1996).

Although Plaintiffs cite *Wyeth v. Lupin Ltd.*, 252 F.R.D. 295, 297 (D. Md. 2008) to support their argument, that case is also readily distinguishable. *See* Mem. at 3. In that case, the court held that a Rule 30(b)(6) designee cannot offer “amendments” or “corrections” materially alter her testimony through Rule 30(e) errata changes. *Id.* at 297. Because no such “amendments” or “corrections” are at issue here, *Lupin* is simply inapposite.

Finally, setting aside the fact that the weight of authority expressly rejects the interpretation of Rule 30(b)(6) articulated in *Rainey v. American Forest & Paper Association, Inc.*, 26 F. Supp. 2d 82, 94 (D.D.C. 1998), Ethicon would still not be precluded from offering Dr. MacLean’s opinions at trial under the holding in that case. *Rainey* held that a corporate entity is bound by Rule 30(b)(6) testimony “[u]nless it can prove that the information was not known or was inaccessible” at the time of the deposition. *Id.* Here, Dr. MacLean’s opinions are based on his control experiments and analysis of Dr. Iakovlev’s use of histological stains, all of which was conducted after Dr. Barbolt’s Rule 30(b)(6) deposition in January 2014. Thus, even under *Rainey*, Ethicon would not be bound by Dr. Barbolt’s allegedly contradictory testimony because Dr. MacLean’s analysis “was not known or was inaccessible” when Dr. Barbolt testified.

CONCLUSION

For all of the reasons identified in its *Daubert* Response filed in relation to Dr. MacLean for Ethicon Wave 2, Dkt. 2552, which Ethicon adopts and incorporates by reference, as well as those discussed above, the Court should deny Plaintiffs’ Motion to Exclude or Limit the Opinions and Testimony of Steven MacLean, Ph.D., P.E.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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